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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,348	12/01/2000	Ying-Fei Wei	PF220P1	3638
22195	7590	12/19/2003	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			SPECTOR, LORRAINE	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 12/19/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,348

Applicant(s)

WEI, YING-FEI

Examiner

Lorraine Spector, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/24/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 26-79 are under consideration.

Claim Objections

Applicant is advised that should claims 72-75 be found allowable, claims 76-79 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicants have traversed this objection on the grounds that claims 72-75 require “a fragment”, whereas claims 76-79 require “the active site”. This argument has been fully considered but is not deemed persuasive because claims 72-75 require “a fragment...wherein said fragment stimulates aortic smooth muscle cell proliferation”, whereas the latter claims recite “comprising the active site”. The Examiner is at a loss as to how these claims differ, as the “active site” would be taken, in view of the specification, to be that portion of the molecule that is capable of stimulating aortic smooth muscle proliferation. It is this interpretation upon which the claims have been examined. Applicants have indicated otherwise in their traversal, however they have not proffered any alternate interpretation of the claims. Should applicants present any alternative interpretation at this time, such would require the Examiner to reject the claims as being indefinite under 35 U.S.C. §112, second paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-59 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein of SEQ ID NO: 2 or as encoded by ATCC

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97342 or fragments thereof that have the activity of stimulating the growth of aortic smooth muscle cells, does not reasonably provide enablement for proteins 90% or 95% identical to such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for reasons set forth in paper number 18 at pages 3-4. This rejection is maintained for reasons of record.

Applicants argue that Pages 10-11, Table I and Figures 2-3 provide adequate guidance as to where the protein could be modified. This argument has been fully considered but is not deemed persuasive because it remains that the specification merely presents an invitation to experiment to find variants, as opposed to specific guidance or working examples of variants. It remains that although proteins that bind and activate EGF receptors were known in the art, and the relative skill in the art of molecular biology is high, the predictability in the art of altering proteins and retaining function is relatively low, especially where, as in this case, the members of the protein family which bind EGF receptors have a low degree of conservation of amino acid sequences. In this case, the similarity to TGF α shown in Figure 2 is very low, and it has not been established that TGF H3 binds to the common receptor, the EGF receptor. Taken with the lack of working examples, the lack of *specific* direction or guidance as to alterations which could be made, the breadth of the claims, which in their current state read on a very large scope of proteins, the specification fails to provide enablement commensurate in scope with the claims.

Applicants further argue that the specification provides methods of assaying the activity of variants and raising antibodies thereto. This argument has been fully considered but is not deemed persuasive because a method of assaying is not a method of making. It remains that the specification is a mere invitation to experiment by making a set of substitutions chosen randomly from the millions of possible substitutions without direction or guidance as to which would be expected to maintain activity, and that such a process would, in the express absence of specific direction or working examples, require undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 26, 28-33, 36-40, 42-43 45-50, 53, and 56-63 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/18203 (Kato et al.), cited by applicants.

Claims 27, 34, 35 41, 44, 51, 52, 54, 55, and 64-79 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/18203 (Kato et al.), cited by applicants.

SEQ ID NO: 7 of Kato et al. is identical to SEQ ID NO: 2 of the instant application. Fragments are disclosed at page 7, and recombinant expression of protein is disclosed, as are fusion proteins and compositions comprising a carrier, see pages 4-7, 9 and 11-14, respectively. The property of stimulating aortic smooth muscle cell proliferation is inherent to the protein of Kato et al.

Applicants have argued that priority should be granted to the filing date of the parent application, 08/778545, and the provisional application 60/168387. This argument has been fully considered but is not deemed persuasive because with respect to the 08/778545 application, the case is still under rejection for lack of utility and enablement. Until such rejection is withdrawn by the Examiner or reversed by the Board of Appeals and Interferences, it remains that the parent case lacks utility and enablement. With respect to the provisional application, 60/168387, the publication date of the Kato et al. reference was April 15, 1999. As such, since the provisional application is found to have utility and enablement for the currently claimed subject matter, the Kato reference is now applied under 35 U.S.C. §102(a) for those claims that are directed solely to the full-length polypeptide, or the polypeptide "lacking a signal sequence", as would have been produced by the transformed cells therein; there appears to be no basis for peptides comprising amino acids 1-204 of SEQ ID NO: 2 or 1-177 of SEQ ID NO: 2 in the

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provisional application. Similarly, applicants have not pointed out basis for claim 33 part (c) in the provisional application, nor for the peptide of claim 60. Accordingly, those claims are not granted priority to the provisional application.

Conclusion

No claim is allowed.

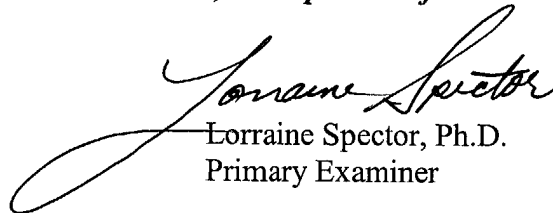
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number will be 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623. ***Effective 1/21/2004, Dr. Kunz' telephone number will be 571-272-0887.***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228. ***Effective 1/21/2004, Dr. Spector's fax number will be 571-273-0893.***


Lorraine Spector, Ph.D.
Primary Examiner

12/16/2003